

U.S. Application Serial No. 10/040,830  
Attorney Docket No.: 33677-00700

### ***REMARKS***

Applicants thank the Examiner and her supervisor for their time and consideration during the telephone interview conducted on May 25, 2004. Applicants have carefully considered the non-final Office Action mailed November 26, 2003 and submit the following Amendment and Response in reply thereto. Reconsideration and withdrawal of the outstanding rejections is respectfully requested. Applicants believe that the amendments presented herein place the application in condition for allowance and early notice to that effect is urgently requested.

### ***Status of the Claims***

Upon entry of the foregoing amendment, claims 16-19 will be pending.

### ***Information Disclosure Statement***

Applicants acknowledge, with appreciation, receipt of a signed and fully initialed copy of the PTO form 1449 filed January 8, 2002.

### ***Election/Restriction***

The Office Action mailed June 24, 2003 required a restriction and an election of species. In response, Applicants elected methods of treating pain caused by neuralgia using botulinum toxin. The first group of alleged species set forth in the Office Action listed species A as trigeminal neuralgia and species B as facial pain.

Applicants have carefully considered the species requirement as it was put forth in the Office Action and respectfully submit that the requirement of an election of species between

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trigeminal neuralgia and facial pain was improper. Applicants respectfully request reconsideration of this requirement for the following reasons.

As set forth in Applicants' description of the invention, trigeminal neuralgia is a *cause* of facial pain (see page 3, Summary of the Invention). Thus, the relationship between trigeminal neuralgia and facial pain is one of *cause* and *effect*. Applicants respectfully assert that trigeminal neuralgia and facial pain are not species within a genus and should therefore not be treated as such. The M.P.E.P. at 806.04(f) describes the test for determining how to recognize claims as being restricted to different species as follows:

Claims to be restricted to different species must be mutually exclusive. The general test as to when claims are restricted, respectively, to different species is the fact that one claim recites limitations which under the disclosure are found in a first species but not in a second, while a second claim recites limitations disclosed only for the second species and not the first. This is frequently expressed by saying that claims to be restricted to different species must recite the mutually exclusive characteristics of such species.

In the instant case, trigeminal neuralgia and facial pain are not related to one another as species because they are not mutually exclusive. Trigeminal neuralgia is a *cause* of facial pain and the relationship between the two is one of *cause* and *effect*. Trigeminal neuralgia and facial pain are not species of one another and should not be treated as such. Applicants respectfully assert that it would be unfair to maintain the species requirement as originally set forth because it has the potential of precluding from patentability that which applicants have invented, namely, methods of treating facial pain caused by trigeminal neuralgia. Reconsideration and withdrawal of the species election requirement, at least as far it pertains to the characterization of trigeminal neuralgia and facial pain as being species of one another, is respectfully requested.

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***Claim Objections***

Applicants note that the originally filed claims were mis-numbered and that the mis-numbered claims were renumbered as claims 1-15. Applicants have cancelled original claims 1-15 without prejudice or disclaimer and added new claims 16-19. The objection is therefore moot.

***The Rejection of Claims 1, 8-9 and 11 under 35 U.S.C. § 102(e)***

Claims 1, 8-9 and 11 stand rejected under 35 U.S.C. § 102(e) for allegedly being anticipated by U.S. Pat. No. 6,464,986 to Aoki *et al.* (the '986 patent). Applicants respectfully traverse the rejection insofar as it may be applied to new claims 16-19.

The '986 patent is directed to methods for treating pain by peripheral administration of a neurotoxin. The Office Action mailed November 26, 2003 sites column 24, Example 3, which is directed to a method for treating post herpetic neuralgia, and alleges that the '986 patent anticipates the claims. Applicants respectfully assert that nothing in the '986 patent anticipates or renders obvious the presently pending claims because there is no teaching or suggestion anywhere in the '986 patent of the claimed methods for treating facial pain caused by trigeminal neuralgia. Post herpetic neuralgia is not trigeminal neuralgia and the two are recognized as being distinct by those having skill in the art. See the article by Olesen which is attached hereto. Table 1 in this reference is titled "Classification of headache disorders, cranial neuralgias, and facial pain" and the table clearly distinguishes post herpetic neuralgia (classification number 12.1.4.2) and trigeminal neuralgia (classification number 12.2).

In fact, there is simply no teaching or suggestion of methods for treating facial pain caused by trigeminal neuralgia anywhere in the '986 patent. Respectfully, facial pain caused by

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trigeminal neuralgia is an accepted distinct clinical syndrome with unique diagnostic criteria and etiology (causes). A person having ordinary skill in the art would not confuse facial pain caused by trigeminal neuralgia with other states associated with pain.

Applicants submit that a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Vandergaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The presently pending claims are directed to methods of treating facial pain caused by trigeminal neuralgia and there is no teaching or suggestion of such a method anywhere in the '986 patent. The '986 patent cannot anticipate the pending claims because it does not teach or suggest the limitations present in the claims. Withdrawal of the rejection is requested.

***The Rejection of Claims 1-2, 8-9 and 11 under 35 U.S.C. § 102(b)***

Claims 1-2, 8-9 and 11 stand rejected under 35 U.S.C. § 102(b) for allegedly being anticipated by U.S. Pat. No. 5,714,468 to Binder (the '468 patent). Applicants respectfully traverse the rejection insofar as it may be applied to new claims 16-19.

The '468 patent is directed to methods for reduction of migraine headache pain by delivering an invertebrate presynaptic neurotoxin to a mammal. Nowhere in the '468 patent is there any teaching or suggestion of methods for the treatment of facial pain caused by trigeminal neuralgia. In fact, the specification and claims of the '468 patent repeatedly characterize the invention as being drawn to methods for the reduction of headache pain (see, for example, the Abstract; column 1, lines 14-15; column 4, lines 6-7; Example 1; and claims 1, 11-13 and 21).

Respectfully, facial pain caused by trigeminal neuralgia is an accepted distinct clinical syndrome with unique diagnostic criteria and etiology. A person having ordinary skill in the art

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would not confuse facial pain caused by trigeminal neuralgia with migraine headache. For example, the International Headache Society (IHS) has adopted an internationally accepted headache classification scheme directed to operational criteria for diagnosis of pain. This classification scheme has been translated into multiple languages and is internationally recognized (see J. Olesen, "Classification of Headache" Chapter 2, *The Headaches*, Second Edition, Lippincott, Williams and Wilkins. Eds. Olesen, Hansen & Walsh. Philadelphia, 1999, copy enclosed with attached Information Disclosure Statement). In the classification system, migraine headache is classified in Group 1 while trigeminal neuralgia is classified in category 12.2. Thus, trigeminal neuralgia is distinctly different from migraine headache and is recognized as such by those having skill in the art.

Differences in diagnostic criteria for pain are also recognized by health care professionals. For example, insurance companies use coding systems specific for different disease entities. Such coding systems draw a distinction between trigeminal neuralgia and migraine and tension headaches. See attached copy of the Alabama Blue Cross and Blue Shield Policies regarding uses of botulinum toxin for pain. The policy mandates a distinction between migraine and trigeminal neuralgia. The policy also approves botulinum toxin for trigeminal neuralgia as medically necessary (page 2) while holding the migraine application as investigational (page 3). Thus, trigeminal neuralgia is recognized as being distinct from migraine headache by those having skill in the art.

Applicants submit that a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.

*Vandergaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The presently pending claims are directed to methods of treating facial pain

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caused by trigeminal neuralgia and there is no teaching or suggestion of such a method anywhere in the '468 patent. The '468 patent cannot anticipate the pending claims because it does not teach or suggest the limitations present in the claims. Withdrawal of the rejection is requested.

***Conclusion***

Applicants respectfully request reconsideration and withdrawal of the pending rejections and early allowance of the pending claims. Should the Examiner find that a telephone interview would further prosecution of the application, she is invited to contact the undersigned at her convenience.

The Commissioner is authorized to charge any additional fees associated with this filing, or credit any overpayment, to Deposit Account No. 13-3250. **EXCEPT** for issue fees payable under 37 C.F.R. § 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§ 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 13-3250. This paragraph is intended to be an **CONSTRUCTIVE PETITION FOR EXTENSION OF TIME** in accordance with C.F.R. § 1.136(a)(3).

Respectfully submitted,

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